

REMARKS

It is respectfully requested that this application be reconsidered in view of the above amendment and the following remarks and that all of the claims remaining be allowed.

Claim Amendments

Claims 1-9 have been canceled without prejudice or disclaimer. (Claims 10-20 had been previously canceled in response to a requirement for restriction.) Applicants specifically reserve the right to file one or more continuing application(s) to prosecute the canceled subject matter.

New claims 21-38 have been added, support for which can be found, for example, as follows:

Claim Number	Exemplary Support
21	Page 8, line 30 to page 9, line 2; page 6, lines 8-12; original claim 1
22-29	Original claims 2-9
30	Page 8, line 30 to page 9, line 2; page 6, lines 8-12; original claim 1
31-38	Original claims 2-9

No new matter has been added by these amendments. The Examiner is hereby requested to enter these amendments.

Applicants wish to thank Examiner A. Chakrabarti for the courtesy of discussing the present application over the telephone with the undersigned as well as providing helpful suggestions in April and May, 2003. Applicants respectfully submit that the amendments and remarks herein reflect the suggestions and discussion during the interviews, thereby placing this application in condition for allowance.

Applicants submit that all claim amendments presented herein or previously are made solely in the interest of expediting allowance of the claims and should not be interpreted as acquiescence to any rejections or ground of unpatentability. Applicants reserve the right to file at least one continuing application to pursue any subject matter that is canceled or removed from prosecution due to the amendments.

Rejection Under 35 U.S.C. §103:

(a) *Anderson in view of Yan*

The rejection of claims 1-5 under 35 U.S.C. §103 over Anderson (U.S. Patent No. 6,242,213 B1) in view of Yan (U.S. Patent No. 5,856,928) is now moot since claims 1-5 have been canceled.

New claims 21-38 are now pending in this application. Applicants respectfully submit that none of the currently pending claims are subject to this rejection for the reasons set forth below.

To properly issue a rejection under 35 U.S.C. §103, the USPTO bears the initial burden to establish a prima facie case of obviousness by meeting three criteria. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to arrive at the claimed invention. *In re Vaeck*, 20 USPQ 2d 1438 (Fed. Cir. 1991). Second, there must be a reasonable expectation of success. *Id.* Finally, the prior art reference or the combination of references must teach or suggest all the claim limitations. *In re Royka*, 180 USPQ 580 (CCPA 1974).

A rejection of any of claims 21-38 under 35 U.S.C. §103 over Anderson in view of Yan would not meet the required criteria. For example, claim 21 is directed to a coiled-coil polypeptide comprising the formula $(ab_i c_i d_i e_i f_i g_i)_n$, where $i=1,2,\dots,n$, and n is at least three, said polypeptide being prepared by

- (a) independently inserting an amino acid selected from the group consisting of leucine, isoleucine, valine, phenylalanine, methionine, tyrosine, and derivatives thereof, into each of the *a* and *d* positions; and
- (b) selecting a solvent-accessible region of an epitope of a selected natural protein, wherein said region is not in a coiled-coil conformation in its native state, and inserting the amino acids from said region into the *b_i*, *c_i*, *e_i*, *f_i* and *g_i* positions;

wherein $(ab_i c_i d e f_i g_i)_n$ forms a coiled-coil.

Therefore, the claimed invention pertains to a coiled-coil polypeptide which is prepared using a coiled-coil template, from a protein region that is not in a coiled-coil conformation in its native state.

Anderson teaches the sequence of and compositions comprising RANK-L, an immune regulator. In teaching the various fusion proteins comprising RANK-L, Anderson discloses that RANK-L may be fused with a leucine zipper domain (column 5), and that the leucine zipper domain forms a coiled-coil (column 6). Anderson does not teach or suggest changing any protein region that is not in a coiled-coil conformation in its native state into a coiled-coil polypeptide using a coiled-coil template.

The Yan reference teaches a numerical method for the analysis of sequence information of DNA, RNA and proteins. Thus, each kind of nucleotide base, base pairing and amino acid is assigned a number, and a DNA, RNA or protein can be represented, characterized and interpreted by sums of the numbers assigned to its constituent nucleotide, base pairing or amino acid. Many examples were used to illustrate this method. In one of the examples, the numerical sums were deduced for the prion proteins, and Yan concluded that prion proteins are fibrous chains like those in Type I collagen, silk fibroin, fibrinogen or tropomyosin (column 40, lines 47-48). Yan further discloses that most of these fibrous protein strands aggregate through hydrogen bond zippers (column 40, lines 49-50) and are gelling proteins which are either wound-healing or disease-causing agents (column 40, lines

58-59). Yan does not teach or suggest changing any protein region that is not in a coiled-coil conformation in its native state into a coiled-coil polypeptide using a coiled-coil template.

In view of the disclosure of Anderson and Yan, there would not be any suggestion or motivation to combine these two references and modify the reference teachings to arrive at the claimed invention. Furthermore, the combination of the two references does not offer a reasonable expectation of success, or teach or suggest all the claim elements. As discussed above, neither reference teaches, suggests, or even relates to changing a non-coiled-coil protein region into a coiled-coil using a coiled-coil template. Combining the references does not cure the deficiency.

Accordingly, a rejection of the claimed invention in view of Anderson and Yan would not satisfy the requirement under 35 U.S.C. §103.

(b) Anderson in view of Yan further in view of Prusiner et al.

The rejection of claims 6-9 under 35 U.S.C. §103 over Anderson (U.S. Patent No. 6,242,213 B1) in view of Yan (U.S. Patent No. 5,856,928) and further in view of Prusiner et al. (U.S. Patent No. 5,792,901) is now moot since claims 6-9 have been canceled. Therefore, withdrawal of this rejection is respectfully requested.

Furthermore, Applicants wish to point out that none of the currently pending claims would be subject to this rejection for the reasons set forth below.

A rejection of any of the pending claims over Anderson in view of Yan and further in view of Prusiner would also fail to satisfy the three criteria set forth above as required under 35 U.S.C. §103. It has been discussed above that the claimed invention pertains to a coiled-coil polypeptide which is prepared using a coiled-coil template, from a protein

region that is not in a coiled-coil conformation in its native state. It has been further discussed that the combination of Anderson and Yan does not teach or suggest the claimed invention in any way. The Prusiner et al. reference fails to correct these deficiencies.

Prusiner et al. teach an artificial prion protein gene, transgenic animals harboring the prion protein gene, and certain methods of using the prion protein gene. The reference does not teach or suggest changing a protein region that is not in a coiled-coil conformation in its native state into a coiled-coil polypeptide. In fact, Prusiner et al. do not discuss the coiled-coil protein conformation at all. Therefore, there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to arrive at the claimed invention. Nor is there a reasonable expectation of success. The combination of the three references also does not teach or suggest all the claim elements. Clearly, the requirement under 35 U.S.C. §103 would not be met.

Accordingly, Applicants respectfully submit that the currently pending claims are not subject to this rejection, or any other rejection.

Conclusions:

For the reasons set forth above, Applicants submit that the claims of this application are patentable. Reconsideration and withdrawal of the Examiner's rejections are hereby requested. Allowance of the claims remaining in this application is earnestly solicited.

Amendment and Reply to Office Action

Application No. 09/603,832

Attorney's Docket No. 003592-012

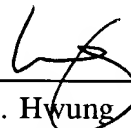
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In the event that a telephone conversation could expedite the prosecution of this application, the Examiner is invited to call the undersigned at (650) 622-2300.

Respectfully submitted,

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